UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,246	07/28/2006	Alastair David Griffiths Lawson	13001011PCTUS	9639
23565 KLAUBER & J	7590 03/13/2009 JACKSON	109	EXAMINER	
411 HACKENS	SACK AVENUE		WEN, SHARON X	
HACKENSACK, NJ 07601			ART UNIT	PAPER NUMBER
			1644	
			MAIL DATE	DELIVERY MODE
			03/13/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Art Unit: 1644

Applicant's arguments, filed 02/27/2009, have not been found convincing essentially for the reasons of record.

In response to Applicant's argument on that the recitation "a marker which is essentially unique" to an antibody-producing cell meet the requirement for written description because a skilled person could do a literature search to identify a marker that is specific or very highly expressed on the cell types being considered, the following is noted.

It is acknowledged that identifying a marker for a particular type of cells is routine in the art. However, it is noted that an adequate written description of a chemical inventions also require a precise definition such as by structure, formula, chemical name, or physical properties, and not merely a wish or plan for obtaining the chemical invention claimed. See, e.g., *Univ. of Rochester v. G.D. Searle & Co.*, 358F.3d 916,927,69 USPQ2d 1886, 1894-95.

In this case, while it is routine to identify a cell marker, given the plethora of cell surface markers and the non-limiting definition of these "essentially unique" markers, one skilled in the art cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus of the markers that exhibit this functional property because these species do not share a common structure drawn to a common function, i.e., essentially unique to antibody-producing cell. For example, CD45 is not limited to B cell, but also appears on T cell. Therefore the specification does not provide sufficient written support for the genus of markers recited in the claims.

Applicant's argument has been considered in full but not found convincing.

Therefore, the rejection of record is **maintained** for the reasons of record, as it applies to the amended and newly added claims. The rejection of record is incorporated by reference herein, as if reiterated in full.

In response to Applicant's argument that combination of Chang, Goldsby and Brezinsky does not render obvious of the present claims, the following is noted.

Chang discloses the following (column 5, lines 18-53):

Art Unit: 1644

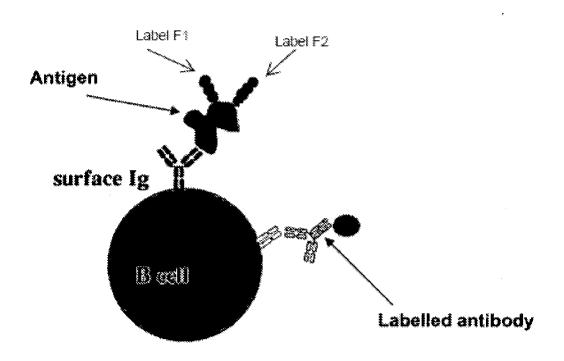
The invention includes methods that increase the likelihood that antibodies expressed by a single B cell selected by a fluorescence-sorting technique, FACS, are specific for the antigen of interest, and that also allow selection of B cells expressing antibodies of high affinity for the antigen of interest. The sorting for B cells expressing antibodies to specific antigens is increased by labeling B cells with at least two antigen probes, where each antigen probe includes the antigen of interest and the difference between the two probes is that each is labeled with a different fluorochrome, F1 and F2 respectively. Also, to futher increase the specificity of the selected B cells, it is preferred if, when cross-linkers or carrier molecules are employed in the conjugation of antigen to fluorochrome, different cross-linkers and carrier molecules are used for each of the two antigen probes.

Page 3

The specificity of sorting of the desired B cells can be further enhanced by labeling those B cells which produce the immunoglobulin isotype (typically IgG) of interest. The surface antigens suitable for labeling are the .gamma. chain, .kappa. or .lambda. chains, CD19, Ia, and the Fc receptors. This labeling of antigens on the B cells is preferably done with one or more targeting molecules, each being associated with one of two fluorochromes. For example, affinity-purified IgG-F(ab').sub.2 of goat-antihuman IgG (.gamma. chain) conjugated with fluorochrome F3 and affinity purified IgG-F(ab').sub.2 of rabbit-anti-human CD19 conjugated with fluorochrome F4 can be used. Either or both of these additional labeled targeting can be applied with the two labeled antigen probes described above. Thus, the antigen-specific IgG-producing B cells of interest may be labeled with these unique reagents in three or even four-color FACS, which can sort enhanced proportions of the desired antigen-specific B cells.

Upon reading the above sections, in particular the bolded sections, taught by Chang, one of ordinary skill in the art would have readily visualized the following wherein the antigen of interest is labeled by two fluorochrome labels, F1 and F2:

Art Unit: 1644



Therefore, the difference between Chang and the present claims was that the Chang's antigen was directly labeled whereas the antigen of interest in the present invention was indirectly labeled by a polyclonal antibody that recognized the antigen, wherein the polyclonal antibody was labeled.

This difference of direct labeling and indirect labeling with polyclonal was cured by Goldsby as stated in the previous Office Action.

Applicant's argument has been considered in full but not found convincing.

Therefore, the rejection of record is **maintained** for the reasons of record, as it applies to the amended and newly added claims. The rejection of record is incorporated by reference herein, as if reiterated in full.